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09/485,245	03/27/2000	ALISON HOPKINS	28911/36128	1697

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EXAMINER

WILDER, CYNTHIA B

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/485,245

### Applicant(s)

HOPKINS, ALISON

### Examiner

Cynthia B. Wilder, Ph.D.

### Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 7, 2003 has been entered. Claims 1, 3-6 have been canceled. Claims 7-10 have been added. Claims 7-10 are pending.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 7-10 are indefinite because the claims as written do not provide a nexus between the step of forming a solution of random mixture of oligonucleotides and a method for the prevention of self-annealing. It cannot be determined how a single step of "forming a solution of a random mixture of oligonucleotides which are 6 mers to 8-mers..." results in a method of preventing self-annealing. Likewise, it cannot be determine if the claimed method is intended to recite a method of forming a solution of random mixtures of oligonucleotides or a method of preventing self-annealing. Clarification is required as to Applicant's intent.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godiska et al. (5,759,804, filed November 17, 1993) in view of Shen et al. (EP 0 726 310 A1 February 09, 1996). Regarding claims 7-10, Godiska et al teach a method comprising a random mixture of oligonucleotides which are 6-mers, wherein the composition further contains at least a supply of nucleotides for chain extension, a labeled nucleotide, and a polymerase enzyme (col. 8, lines 27-31). Godiska et al differs from the instant invention in that Godiska et al do not expressly teach wherein the solution comprising the random mixture of hexamers is in a freeze-dried state. Shen et al teach a composition similar to that of Godiska et al present in a dry state (page 4, lines 37-41). Shen et al teach wherein the composition may comprise primers, a polymerase enzyme, a supply of nucleotides for chain extension, and a stabilizer (page 6, lines 3-7 and 22). Shen et al teach that the composition present in the dry state is advantageous because the composition is stable for a prolonged period, even when stored at high temperature. Shen et al further teach that a composition in a dried state is useful in shipping and storage of commercial preparations for use in e.g., nucleic acid amplification kits (page 6, lines 39-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have been motivated to have provided a random mixture of hexamers in the method as taught by

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Godiska et al in a dried state. One of ordinary skill in the art would have been motivated to do so for the advantage taught by Shen et al that a nucleic acid composition (such as primers) present in a dried state is useful in shipping and storage of commercial preparations due its increase stability.

***Applicant's Traversal***

6. Applicant traverses the rejection on the following grounds: Applicant states that the obviousness rejections against new claims 7-10 should be withdrawn because the art fails to teach the desirability of short primers in a dried primer system or that 6-mer to 8-mers would behave differently with respect to self-priming activity and labeling intensity than do 9-mers. Applicant states that more specifically, there is nothing in Godiska that teaches that selections of 6-mers to 8-mers constitute a critical range and that short primers would be desirable in a dried primer system. Applicant contends that while Godiska discloses a random mixture of 6-mers and other ingredients the examiner acknowledges that Godiska does not teach a labeling composition in a dry state. Applicant contends that moreover, there is nothing in Godiska that teaches that the selections of 6-mers to 8-mers is important in either the liquid or freeze dried state to reduce self-annealing. Applicant states that in fact, self-annealing is not mentioned at all. Applicant states that in addition, Shen, which discloses 48-mer and 22-mer primers (Example 1 and SEQ ID NOS: 1 and 2) fails to suggest that dried primers should be shortened or alternatively any reason why the primers of Godiska should be dried. Applicant states that this is because the prior art generally taught that longer primers were preferred because longer primers have higher melting temperatures and are this more specific. Moreover, Shen acknowledged that "whether a particular composition will function to preserve biological activity for a

particular biologically active material is not a priori predictable" and only discloses freeze-drying as an option and in addition, Shen fails to provide any reason why the primers of Godiska should be dried given the fact that shorter primers were thought to be inherently more stable and there was no reason to believe that the shorter Godiska primers would benefit from being in freeze-dried kits. Applicant finally concludes that for these reasons, the rejections under 35 USC 103(A) should properly be withdrawn and not repeated against method claims 7-10.

***Examiner's Response***

7. Applicant's arguments filed on November 7, 2003 have been fully considered but they are not persuasive. With respect to Applicant's arguments that the cited references do not apply, it is noted that the courts have established that during patent examination, the claims must be interpreted broadly as reasonably allow (*In re Zletz*, 893 F.2d321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)). In this case the claims as broadly written are not limited in the way Applicant contends. The claims as written do not provide a nexus between a method of preventing self-annealing and a random-mixture of oligonucleotides that are 6-mers to 8-mers. The claims do not circumscribe how forming a mixture of random oligonucleotides that are 6-mers to 8-mers in a dried state or solution results in the prevention of self-annealing in a random mixture of oligonucleotides. Thus the claims do not describe the steps or characteristics which distinguishes them from the prior art. It is noted that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Unexpected results as indicated by Applicant must correlate with the invention as provided in the specification. While the claims broadly recite forming a solution of a random

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mixture of oligonucleotides which are 6-mer to 8-mers in a dried state, the specification further teaches that the percentage or rate of dCTP incorporation is critical to the self-priming abilities of the primers that are 6-mer to 8-mer versus primers that are nanomers. The claims of the instant invention must make clear the discovery of the unexpected results as supported by the specification as originally filed.

***Conclusion***

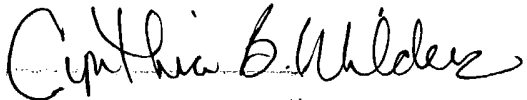
7. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to [cynthia.wilder@uspto.gov](mailto:cynthia.wilder@uspto.gov). Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

Cynthia B. Wilder, Ph.D.

1/23/04

  
CYNTHIA WILDER  
PATENT EXAMINER